Radiology

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FDA Review of Radiologic AI Algorithms: Process and Challenges

Kuan Zhang, PhD • *Bardia Khosravi, MD, MPH, MHPE* • *Sanaz Vahdati, MD* • *Bradley J. Erickson, MD, PhD*

From the Department of Radiology, Mayo Clinic, 200 1st St SW, Rochester, MN 55905. Received February 14, 2023; revision requested March 23; final revision received July 17; accepted July 27. **Address correspondence to** B.J.E. (email: *bje@mayo.edu*).

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A Food and Drug Administration (FDA)–cleared artificial intelligence (AI) algorithm misdiagnosed a finding as an intracranial hemorrhage in a patient, who was finally diagnosed with an ischemic stroke. This scenario highlights a notable failure mode of AI tools, emphasizing the importance of human-machine interaction. In this report, the authors summarize the review processes by the FDA for software as a medical device and the unique regulatory designs for radiologic AI/machine learning algorithms to ensure their safety in clinical practice. Then the challenges in maximizing the efficacy of these tools posed by their clinical implementation are discussed.

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Case Presentation (Dr Kuan Zhang)

An 84-year-old man came to our center's emergency department with confusion and left facial drooping, which started 2 hours earlier. His physical examination was suggestive of acute stroke. To confirm the diagnosis and exclude complications such as hemorrhage, a noncontrast brain CT scan was acquired. Our center has a Food and Drug Administration (FDA)–cleared artificial intelligence (AI)–based triage tool (Aidoc) that analyzes noncontrast brain CT studies and localizes hemorrhage; the result is then communicated to the radiologist. Studies on the diagnostic performance of this type of algorithm have shown high sensitivity and specificity in real-world clinical settings (1,2).

In this case, the algorithm detected an intracranial hemorrhage in the left temporal lobe (Fig 1A). However, the location was not typical for hemorrhagic stroke, and it could not explain the patient's history and physical examination findings. This prompted the radiologist to examine prior patient images, including a noncontrast brain CT scan and a brain MRI scan from 6 months before, which were acquired after an acute episode of dizziness and confusion. The prior CT scan showed a similar hyperintense lesion at the same location (Fig 1B, 1C). Additionally, the fat-saturated postgadolinium MRI sequence showed a dural-based avidly enhancing mass consistent with meningioma (Fig 1D). Ultimately, the patient was diagnosed with a chronic ischemic stroke at MRI (Fig 1E), which also showed a stable small meningioma.

Case Discussion (Dr Bradley J. Erickson)

This scenario highlights a notable failure of AI tools and emphasizes the importance of human review. Current FDA-cleared triage products use only image data (usually from a single time point) (3). This is problematic since, as radiologists, we understand the importance of taking into account prior studies across different modalities, as well as clinical information from electronic medical records, to reach a diagnosis. While there is an urgent need to improve AI tools (eg, to routinely incorporate more information into the model's decision criterion), increasing physician-algorithm interactions is crucial to ensure that possible failures of AI algorithms can be recognized and communicated to avoid clinical errors. This example also alerts the regulatory body to reinforce the audit of any postmarket failures to prevent similar issues in the future.

Conventional Software as a Medical Device and the FDA Review Process

The FDA has guidelines for computer-aided diagnosis (CAD) tools, dating back to 2012 (4). Given the increasing importance and use of software in health care, the term *software as a medical device (SaMD)* is defined by the International Medical Device Regulators Forum to encompass a wide range of software, from those that use the accelerometer in mobile phones to those that monitor patients' balance to denoising algorithms that improve the quality of acquired CT scans (5). SaMDs can be categorized by their intended use (Table) (6).

The current FDA approval process for SaMDs takes a risk-based approach to balance regulatory oversight with the need to promote innovation and patient access to new technologies. Based on the intended use (eg, triage or diagnosis) and the health care condition (ie, critical, serious, or nonserious), four categories from lowest (I) to highest risk (IV) are assigned to reflect the risk associated with the SaMD. Devices presenting lower risk, such as those providing automatic measurement in echocardiograms, may be eligible for the FDA's de novo pathway, which allows for a streamlined review and clearance process. Higher-risk devices, such as those intended for diagnosis or treatment of a disease, may be subject to the 510(k) clearance process or premarket approval, the latter of which is the most stringent review pathway.

In general, a standard 510(k) submission (eg, for class I and II devices based on the risk level) would include a device description, intended patient population and use,

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Abbreviations

AI = artificial intelligence, CAD = computer-aided diagnosis, FDA = Food and Drug Administration, ML = machine learning, SaMD = software as a medical device, SPS = SaMD prespecifications

Summary

A clinical case is presented as an example of a Food and Drug Administration–cleared artificial intelligence tool failure, emphasizing the importance of the human-machine interaction.

Teaching Points

- Current Food and Drug Administration (FDA)–cleared triage products use only image data, usually from a single time point, resulting in an important failure case of artificial intelligence (AI) tools.
- AI/machine learning (ML)–based algorithms differ from conventional software as medical devices (SaMDs) in that their performance changes over the product lifecycle, posing a regulatory challenge.
- Modifications of adaptive AI/ML algorithms that arise could be proactively regulated and monitored by a "predetermined change control plan" designed by the FDA.
- Good ML practice, or GMLP, describes a set of practice expectations of the FDA with respect to data management, training, interpretability, and evaluation.
- Challenges of AI/ML-based SaMDs relate to transparency, clinical evaluation, and consistency.

and technical and clinical performances compared with predicate devices, among others (4). A similar device that is already approved by the FDA is used as the comparison reference by the manufacturer to demonstrate the substantial equivalence of its new device. When an acceptable predicate device in the market cannot be assigned, usually the classification of the device is automatically set to class III, and a premarket approval pathway is required.

Once the SaMD is on the market, postmarket surveillance and reporting are required for all SaMDs to ensure their ongoing safety and effectiveness. When an SaMD manufacturer continuously monitors and collects postmarket information such as safety data, performance results, and clinical feedback, modifications can be made to the algorithm for an improvement of the device. Such a change to the software must go through a similar approval process to ensure the same safety standards (7). This may turn into a burden for AI/machine learning (ML)–based SaMD, given its frequent-adaptive feature.

AI/ML-based SaMD and the FDA Review Process

Historically, AI/ML software analyzing radiologic images was referred to by the same FDA categories, such as CADe, CADx, and CADt (for computer-aided detection, diagnosis, and triage, respectively), which are then used as one of the factors for algorithm risk stratification (eg, CADx has a higher risk than CADe as treated by the FDA) (8). Non-CAD categories also exist, such as medical image management and processing systems. AI/ML algorithms are unique among SaMDs due to their reliance on real-world clinical data to find a pattern for model training. Thus, optimal performance is usually achieved after the algorithm is used, by means of a process called continuous learning (9). This dynamic nature of a model's performance, which is consistently changing over the product lifecycle, poses a regulatory challenge, as the FDA rules are based on static software (10).

A holistic product lifecycle regulatory approach for AI/ML-based SaMD was designed by the FDA to assess manufacturers' reputation in quality and ensure the safety and effectiveness of the product throughout its whole lifecycle. This includes the premarket review, then continued clinical performance evaluation and monitoring following market release (8,10). *Good ML practice*, or GMLP, was termed to describe a set of practice expectations of the FDA with respect to data management, training, interpretability, and evaluation, akin to guidelines from the medical AI community (10,11). Premarket review includes clinical evaluations to ensure a valid association between SaMD and the target clinical problem, the accuracy and reliability of SaMD output with statistical testing, and the achievement of the overall intended purpose of the SaMD.

In addition, the premarket review includes a "predetermined change control plan" specifically for adaptive AI/ML-based SaMD. It is an option for manufacturers to prospectively submit potential modifications during the product lifecycle (8,10). Proposed postmarket modifications could be related to *(a)* performance (eg, retrain with new data or a change in the model architecture), *(b)* inputs (eg, expanding the input data type from CT only to multimodal scans), or *(c)* intended use (eg, from triage to diagnosis or expanding the intended population or disease types). To regulate these potential future changes in the initial premarket review, the predetermined change control plan includes two components, SaMD prespecifications (SPS) and algorithm change protocol.

The FDA recommends manufacturers also submit SPS and algorithm change protocol for the premarket review to provide flexibility, allowing manufacturers to enhance transparency and real-world data collection and monitoring when AI algorithms are being trained continuously. Manufacturers will still need to update and report any modification related to performance, inputs, and intended use but bypass the time-consuming review process. SPS lists the types of anticipated modifications when the SaMD is in use. For example, the AI tool for head CT would expect to retrain with prospective data on the site's acquisition system to improve performance, which can be included in SPS. Meanwhile, the algorithm change protocol records appropriate methods, such as acquisition protocols, data preprocessing, and changes in ML methods or assessment metrics, that the manufacturer anticipates addressing and those modifications listed in SPS. The takeaway message is that by premarket review of these documents, the FDA could build an individualized framework for each SaMD to support monitoring of its future modifications. With controlled risks of new changes, a premarket resubmission may not be required. However, if an SaMD has switched its risk category due to a change in its intended use, resubmission is required (Fig 2). For example, it would be inappropriate for an SPS and algorithm change protocol initially designed for screening mammograms to be leveraged for the final diagnosis of a suspected mass, as the new clinical use case is considerably more critical.

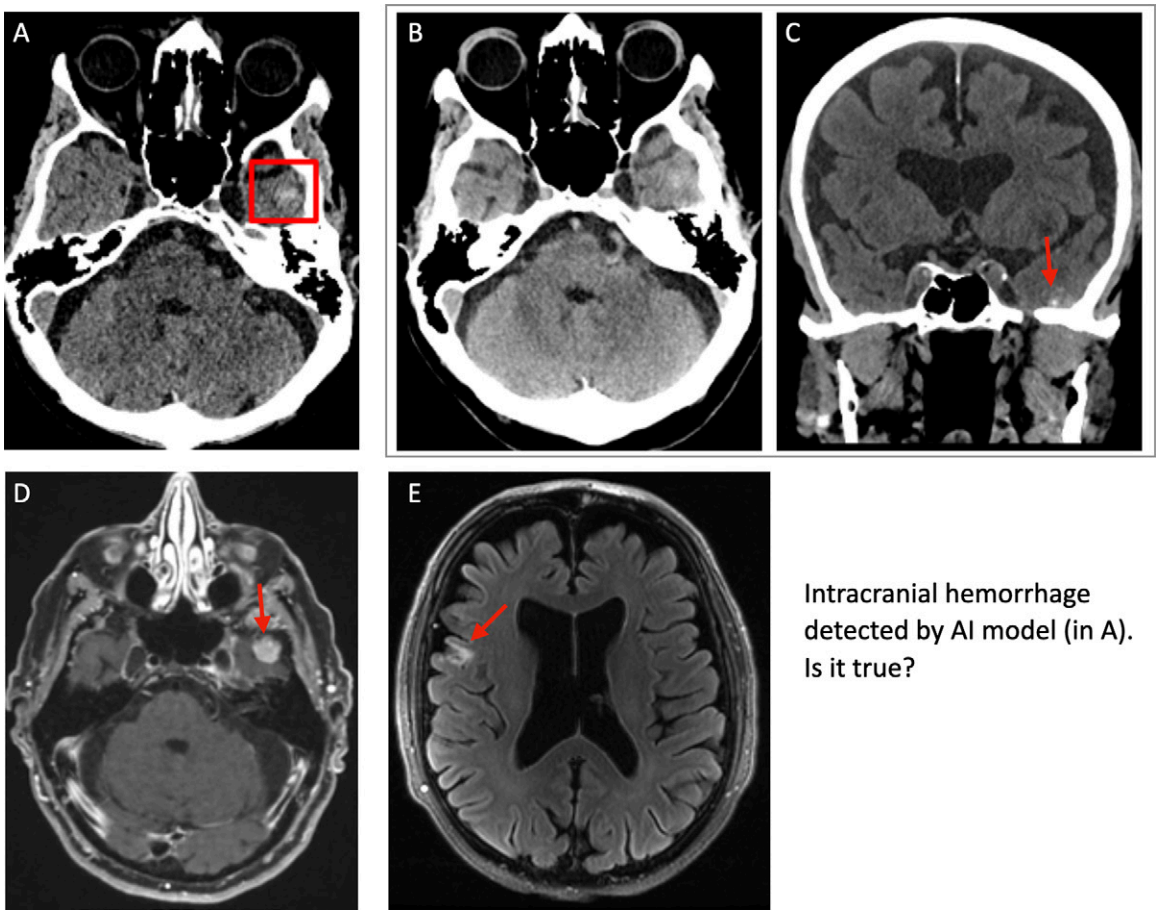

Figure 1: **(A)** Axial noncontrast head CT scan in an 84-year-old man. The artificial intelligence (AI) triage tool flagged the region in the red box as intracranial hemorrhage. **(B)** Axial head CT scan of the same patient from 6 months prior with **(C)** coronal reformat shows a similar signal (arrow). **(D)** Axial T1-weighted postcontrast fat-saturated MRI scan shows a dural-based avidly enhancing mass (arrow) consistent with meningioma. **(E)** Axial T2-weighted fluid-attenuated inversion-recovery MRI scan acquired at the emergency department shows an old ischemic stroke (arrow) but no finding corresponding to the current symptoms.

FDA Categories of Radiologic SaMDs by Their Intended Use, with Descriptions and Radiologic Examples

FDA Category	Definition	Radiologic Examples
CADe	Computer-aided detection	Breast cancer detection in screening mammography; fracture detection
CADx	Computer-aided diagnosis	Lung cancer diagnosis with likelihood of malignant findings
CADt	Computer-aided triage	"First reader" to prioritize critical cases, such as intracranial hemorrhage
CADq	Computer-aided quantification	Volume measurement of tumors and subregions
MIMPS	Medical image management and processing system	MRI reconstruction; segmentation

Note.—Food and Drug Administration (FDA) categories are attached to certain codes of federal regulations. SaMD = software as a medical device.

Challenges of Implementing AI/ML-based SaMD Following FDA Clearance

Given the rapid growth of AI and ML in clinical and radiologic applications, multiple challenges are faced by not only the regulator but also manufacturers and the physicians who use the device in their routine clinical practice. These regulatory, technical, and practical issues, if not addressed efficiently, eventually will harm patients.

An up-to-date data set of FDA-cleared AI/ML SaMDs for radiology would be helpful in defining the salient issues

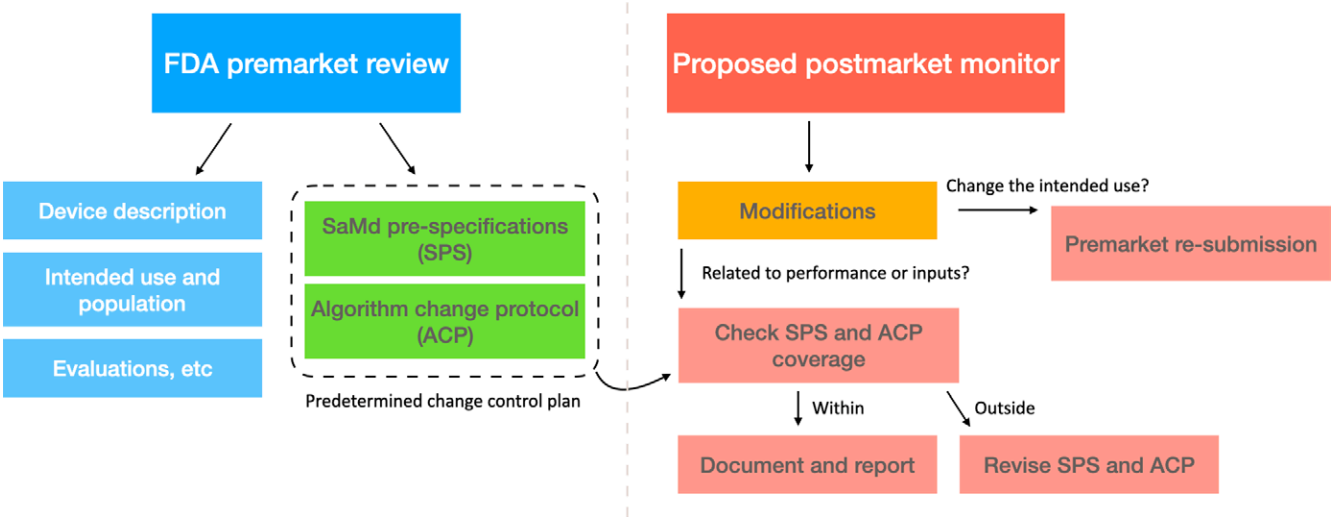

Figure 2: Flowchart of Food and Drug Administration (FDA) pre- and postmarket reviews on artificial intelligence (AI)/machine learning–based software as a medical device (SaMD). A predetermined change control plan encourages manufacturers to include SaMD prespecifications and algorithm change protocol in their FDA application to prospectively list anticipated modifications during the AI product lifecycle and appropriate methods to address these modifications. Premarket review of these documents allows the FDA to build an individualized framework for monitoring each SaMD through future modifications and bypass the time-consuming postmarket review process.

related to their use. Several sources have reported such databases (12,13). Another study has compared AI medical devices between European and U.S. regulatory bodies (14).

We have independently compiled such a database from multiple sources, including data from the FDA's list of devices (15) and non-FDA publicly available resources, such as the American College of Radiology Data Science Institute (16), the Medical Futurist Institute (17), and the Medical AI Evaluation database (12). Our comprehensive search yielded a database of 445 FDA-cleared radiology AI/ML-based SaMDs from May 1, 2008, to November 30, 2022. Figure 3 shows the number of annually cleared cases among different FDA categories. While overall medical image management and processing systems account for most of the cases, the percentage has decayed over the years, indicating a faster growth of the other categories.

One identified challenge relates to the transparency of AI/ML-based SaMD. Supported by the FDA with the term *good ML practice*, manufacturers are encouraged to follow a consensus standard workflow in data handling, model development, and clinical evaluation. Radiologist users of AI/ML-based SaMDs are increasingly pressuring manufacturers to clearly describe in detail the data used to train the model, the definition of the ground truth label, and the intended role of the device in clinical practice. Compared with the conventional SaMDs, AI/ML-based algorithms perform more like a "black box" and can be more vulnerable to modifications and failures during their deployment in clinical settings. The real-world performance could differ from the advertised metrics. For example, the AI tool mentioned in the case scenario was assessed in a retrospective study (18) and shows an inferior performance to a 2nd-year resident under time pressure. Informing the consequence of false-positive predictions, whether the algorithm considers historical examinations, and how the continuous learning would affect its use could help radiologists avoid incautiously trusting the algorithm. It emphasizes the position of the FDA to proactively regulate and monitor these devices. Additionally, disclosure of "ingredients" contained in the SaMD, such as the network architecture, model parameters, and training data, could potentially increase product transparency, similar to the ingredient labels attached to our daily food packages.

Another challenge concerns the clinical evaluation of AI/ML-based SaMD and the consistency between the designed purpose of the device and evaluation metrics under review. Since AI/ML-based SaMDs for the purposes of diagnosis and detection (ie, CADe, CADe/x, and CADx, as shown in Fig 3) have grown much faster than imaging processing and triage tools, this concern is becoming more significant. Metrics such as area under the receiver operating characteristic curve, sensitivity, and specificity are mentioned in the FDA's evaluation guideline (4). In practice, however, SaMD usually serves as an aid to clinicians; thus, the efficacy relies more on the device-clinician interaction than the achieved metric value of the SaMD alone. Such devices, when serving as decision support tools and interacting with a human reader, could display decreased performance after implementation in a health care setting if the reading scenarios (eg, devices performing as the second reader), scoring procedure for data labeling, or study control arm are not appropriately set up (19). Meanwhile, the selection of the reference standard is an issue for some clinical targets where diagnoses may not be clear or their definition changes (20). For example, characterizing postchemotherapy changes in brain tumors as progression versus pseudoprogression is a clinically challenging task for radiologists, and using their reports as ground truth can cause significant biases in the model (21). How will SaMD manufacturers incorporate those new diagnostic definitions in their AI/ML-based algorithms, track the modifications, and update an FDA clearance?

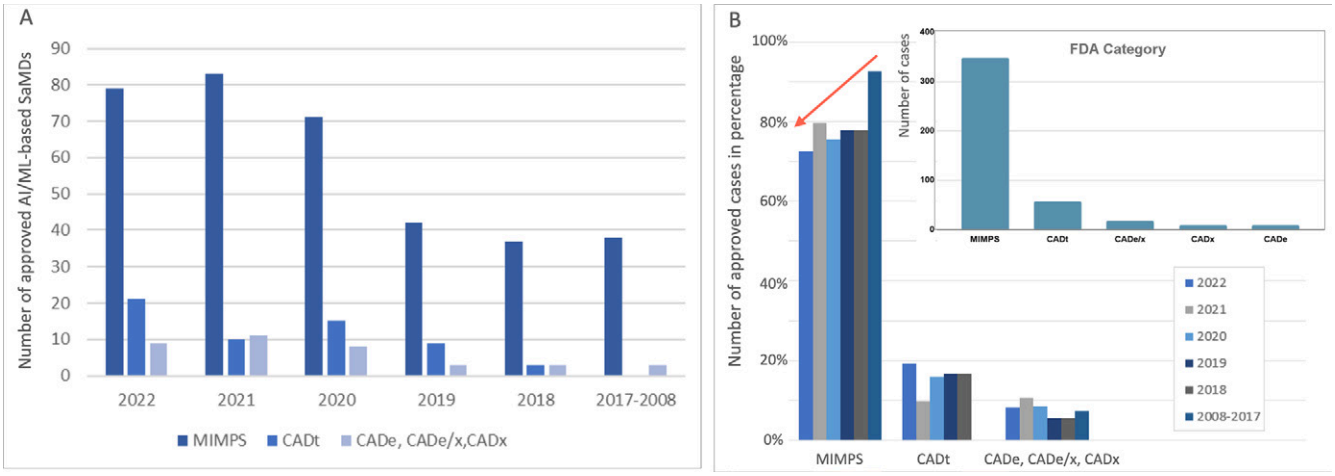

Figure 3: **(A)** Bar graph shows the number of categorical artificial intelligence (AI) tools cleared in each year (from 2008 to 2022). **(B)** Large bar graph shows the percentage of Food and Drug Administration (FDA) categories at different years; the embedded plot in **B** shows case numbers of different FDA categories. CADe = computer-aided detection, CADt = computer-aided triage, CADx = computer-aided diagnosis, MIMPS = medical image management and processing system, ML = machine learning, SaMD = software as a medical device.

A few challenges exist specifically from the manufacturer's perspective. First, current guidelines from the FDA are still ambiguous. Although thoughtful designs on regulations specific to AI/ML-based SaMDs have been proposed, how those plans will be implemented is still not clearly drafted. Correspondingly, procedures for clinical evaluation of AI algorithms are not well documented. Moreover, review periods under the FDA have increased over the years (Fig 4). However, a few cases (76 cases among 444) had an approval period shorter than 60 days. Most of these devices were submitted as an escalated version of previously approved tools either with enhanced performance, as an expansion to other body parts, or as an application to different pathologic abnormalities of the same body part.

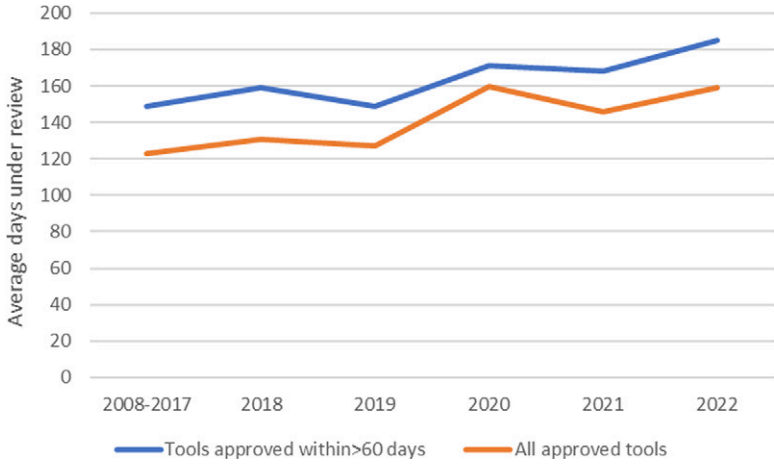

Figure 4: Line graph shows an averaged review period (in days) of cases by year. Despite regulatory designs for artificial intelligence/machine learning software as a medical device, the plot suggests that Food and Drug Administration review periods have increased over the years.

Additional Considerations toward Enhancing Radiologist Trust of AI/ML Tools

To enhance the trust of radiologists to use AI/ML-based tools in their practice, further efforts of clinical evaluation should be focused on the demographic features of the patient population to avoid potential issues related to bias and uncertainty. AI algorithms trained on single-site or retrospective data could generate biased predictions for subpopulations of patients. When the device is applied in a new clinical environment or the patient distribution evolves, it could lead to bias favoring or disenfranchising patients with certain demographic characteristics (22). One could argue that protected features of a patient, such as sex, race, and geodiversity, should be excluded from AI algorithms' input. However, based on the high-dimensional level of learning of AI algorithms with images, the model will still be able to gradually recover these missing sensitive attributes from the intermediate feature layers. Meanwhile, totally demographics-free AI models could perform poorly in practice; demographic information plays a substantial role in making a diagnosis. In light of the above, multicenter and prospective randomized controlled trials are recommended to help manufacturers better control the risks in terms of bias (23,24).

Many radiologists hesitate to use AI tools, as they are doubtful about how confident the predictions are, especially when the device was evaluated on retrospective data and now serves on prospective data. Uncertainty quantification is an approach to examine the trustworthiness of the model by providing confidence scores along with the predictions to address this concern (25). There are two types of uncertainty: aleatoric (data uncertainty) and epistemic (model uncertainty). Aleatoric uncertainty can be due to errors in human annotations (eg, an AI model for head CT was trained on data, some of which may have meningioma mistakenly labeled as hemorrhage, or the bounding box deviated from the true signal). Adding the first type of uncertainty quantification to the devices would assist radiologists in monitoring mismatches or bias in data labeling. Meanwhile, the second type of uncertainty quantification can help with examining the out-of-distribution robustness (eg, some atypical cases

or complications similar to our case presentation may not be included in the training data). Adding the second type of uncertainty quantification could warn the radiologists when the tool is being applied to an unseen case or that adverse changes have happened during continuous learning.

For AI algorithms used for image acquisition or processing, such as reconstruction and denoising methods in MRI scan processing, an open question would be whether and how to design and standardize quality control tests to monitor their performance. Imaging scanners of different modalities are required to undergo quality control tests by medical physicists periodically as a condition for use. An analogous quality control procedure will need to be developed for AI algorithms.

In conclusion, dramatic developments in artificial intelligence (AI) and machine learning (ML) in academics and industry bring both opportunities and challenges. Radiology is in the midst of a sharp transition from AI development to application in clinical practice. The Food and Drug Administration review process specific to AI/ML software as a medical device is in place but will likely continue to evolve. Radiologists should understand the technical, clinical, and regulatory challenges posed by the clinical implementation of these tools to best use them.

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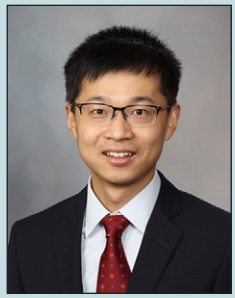
Dr Zhang is an assistant professor of radiology and a 2nd-year diagnostic medical physics resident in the Department of Radiology at Mayo Clinic. His research interests include mathematical modeling, medical imaging AI, and MRI. Dr Zhang teaches undergraduate and graduate courses in modeling and medical imaging AI. He serves as deputy editor of *Radiology* In Training and associate editor of *Radiology Advances*.



Dr Erickson is a professor of radiology and practices neuroradiology in the Department of Radiology at Mayo Clinic. He is also director of the Mayo Clinic AI Lab.